

What is claimed is:

1. A method for the prevention, reduction or treatment of radiation dermatitis comprising the step of applying to an area of skin which has been or will be exposed to radiation, a topical composition which comprises an amount of one or more compounds that regulate at least one of cell differentiation and cell proliferation which is effective, when administered topically in the topical composition, to regulate at least one of cell differentiation and cell proliferation, and an effective amount of one or more antioxidants, formulated in a pharmaceutically acceptable carrier for a topical composition.
2. A method as claimed in claim 1, wherein the one or more compounds that regulate at least one of cell differentiation and cell proliferation is selected from the group consisting of vitamin D<sub>3</sub>, vitamin D<sub>3</sub> analogs and metabolites thereof.
3. A method as claimed in claim 1, wherein the one or more compounds that regulate at least one of cell differentiation and cell proliferation are selected from the group consisting of: vitamin D<sub>3</sub>, 1, 25-dihydroxyvitamin D<sub>3</sub>, 1(S), 3(R)-dihydroxy-20(R)-(1-ethoxy-5-ethyl-5-hydroxy-2-heptyn-1-yl)-9, 10-seco-pregna-5(Z), 7(E), 10 (19)-triene, and other vitamin D<sub>3</sub> derivatives which regulate at least one of cell differentiation and cell proliferation, and pharmaceutically acceptable salts thereof.
4. A method as claimed in claim 1, wherein the one or more antioxidants are selected from the group consisting of: ascorbyl palmitate, ascorbic acid, vitamin A, vitamin E acetate,  $\alpha$ -lipoic acid, coenzyme Q10, glutathione, (-)-epigallocatechin-3-gallate, catechin, galangin, rutin, luteolin, morin, fisetin, silymarin, apigenin, ginkgolides, hesperitin, cyanidin, citrin, curcuminoid, and structurally similar derivatives thereof which exhibit antioxidant activity, and pharmaceutically acceptable salts thereof.

5. A method as claimed in claim 1, wherein the compound that regulates at least one of cell differentiation and cell proliferation comprises vitamin D<sub>3</sub>, and the antioxidant comprises vitamin A, vitamin E acetate, and  $\alpha$ -lipoic acid.

sub  
A/  
cont'd  
5 6. A method as claimed in claim 1, wherein the pharmaceutically acceptable carrier comprises a sufficient amount of at least one non-U.S.P. hydrophilic ointment base to form a substantially topical composition.

7. A method as claimed in claim 6, wherein the pharmaceutically acceptable carrier  
10 further comprises a sufficient amount of a panthenol selected from D-panthenol and DL-panthenol to promote penetration of one or more of the antioxidants and compounds which regulate at least one of cell differentiation and cell proliferation into the skin.

8. A method as claimed in claim 1, wherein the pharmaceutically acceptable carrier  
15 comprises hydroxymethyl cellulose.

9. A method as claimed in claim 1, wherein the pharmaceutically acceptable carrier comprises an acrylic copolymer dissolved in polyethylene glycol.

20 10. A method as claimed in claim 1 wherein the antioxidant comprises one or more antioxidant enzymes.

11. A topical composition for reducing radiation dermatitis comprising:

25 2-9 parts of a dispersion of vitamins A and D<sub>3</sub> in a corn oil base, wherein every cubic centimeter of the dispersion comprises about 500,000 to about 2,000,000 IU of vitamin A and about 50,000 to about 200,000 IU of vitamin D<sub>3</sub>;

1-4 parts of vitamin E acetate;

2-4 parts of ascorbyl palmitate;

1-4 parts of quercetin;

30 0.25-2 parts of  $\alpha$ -lipoic acid; and

a pharmaceutically acceptable carrier, the number of parts of each ingredient being determined independent of the amount of pharmaceutically acceptable carrier present in the topical composition.

Patent 6,666,666